DEA ISO for Auburn

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

NOV 28 2007

IN THE MATTER OF

Cardinal Health
801 C Street NW, Suite B
Auburn, Washington 98001

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RW0191813, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0191813 is assigned to Cardinal Health's Auburn, Washington, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on January 28, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0191813 at 801 C Street NW, Suite B, Auburn, Washington 98001. DEA number RW0191813 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against diversion of a particular controlled substance into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1).

a. Respondent's largest purchaser of combination hydrocodone products in 2007, Horen's Drugstore, Inc. ("Horen's Drugstore"), is a pharmacy engaged in a scheme to dispense controlled substances based on prescriptions that are issued for other than a legitimate medical

purpose and by physicians acting outside the usual course of professional practice. This pharmacy dispensed excessive amounts of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

b. Despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies such as Horen's Drugstore, and despite the public information readily available to Respondent regarding Horen's Drugstore's association with rogue Internet pharmacy websites, Respondent repeatedly supplied Horen's Drugstore with excessive amounts of hydrocodone. Specifically, Respondent distributed in excess of 600,000 dosage units of hydrocodone to Horen's Drugstore from March 2007 through September 2007; including over 116,000 dosage units in July; over 129,000 dosage units in August; and over 122,000 dosage units in September.

c. Respondent, disregarding the clear indications that Horen's Drugstore was engaged in the diversion of controlled substances, distributed unusually large amounts of hydrocodone to Horen's Drugstore. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0191813 is hereby suspended, effective December 3, 2007, at 12:00 p.m. Pacific Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for January 28, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 11/28/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

Date	Time	Diversion Investigator

APPENDIX C

DEA ISO for Lakeland (2007)

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

DEC 05 2007

IN THE MATTER OF

Cardinal Health
2045 Interstate Drive
Lakeland, Florida 33805

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration, RC0182080, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RC0182080 is assigned to Cardinal Health's Lakeland, Florida, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 9, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RC0182080 at 2045 Interstate Drive, Lakeland, Florida 33805. DEA number RC0182080 will expire on May 31, 2008.

2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From August 2005 through October 2007, Respondent distributed over 8,000,000 dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

3. Many of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported prescriptions that are issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from rogue Internet pharmacy websites, in violation of applicable Federal and State law. See United Prescription Services, Inc., 72 FR 50397 (2007).

a. Retail pharmacies in Florida order an average of less than 8,400 dosage units of hydrocodone per month. Respondent distributed hydrocodone to pharmacies engaged in the diversion of controlled substances as reflected in the chart below. Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific and industrial channels.

Pharmacy	Total Dosage Units	Number of Months Distributions Made	Monthly Average	Dates of Distribution (*Distributions not made in every month)
Medipharm-Rx, Inc.	620,030	4	155,007	Aug – Dec 05*
DRM Enterprises, Inc.	929,600	22	42,254	Jan 06 – Oct 07
Jen-Mar Pharmacy Services, Inc.	353,700	11	32,154 1st 3 mos: 2,766 Last 8 mos: 43,175	Mar 06 – Feb 07*
Armenia Pharmacy, Inc.	132,900	12	11,075 1st 6 mos: 1,900 Last 6 mos: 20,250	Mar 06 – Feb 07
National Pharmacy, Inc.	659,800	9	73,311	Aug 05 – May 06*
Parulmed Corporation	468,400	20	23,420	Aug 05 – Apr 07*
Q-R-G, Inc.	1,213,200	5	242,640	Feb – June 06
RKR Holdings, Inc.	741,000	13	57,000	Aug 05 – Jan 07*
United Prescription Services, Inc.	1,148,100	4	287,025	Jul – Oct 06
Satellite Drug and Pharmacy	1,044,000	19	54,947 1st 4 mos: 375 Last 15 mos: 69,500	Feb 06 – Oct 07*

b. Respondent distributed hydrocodone to the pharmacies identified in subparagraph 3.a, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from the

Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

c. Respondent distributed hydrocodone to each of the pharmacies named in subparagraph 3.a, above, and to other pharmacies engaged in Internet diversion schemes, in amounts that far exceeded the legitimate needs of its customers.

d. On September 1, 2006, Eric Brantley, Manager of Quality and Regulatory Affairs for the Respondent, sent an email to DEA's E-Commerce Section stating that the Respondent had discontinued its sales of controlled substances to 13 suspected Internet pharmacies. Included in Respondent's report of discontinued accounts was the aforementioned RKR Holdings, Inc. ("RKR"). On that same date, Respondent distributed 200 dosage units of combination hydrocodone products to RKR. From September 1, 2006, to January 31, 2007, Respondent distributed 393,600 dosage units of combination hydrocodone products to RKR.

4. Respondent repeatedly supplied the pharmacies named in paragraph 3.a, above, and other pharmacies, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding many of its pharmacy customers' association with rogue Internet pharmacy websites, and despite the suspicious nature of the orders placed by these pharmacies. See Southwood Pharmaceuticals, Inc., 72 FR 36487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RC0182080 is hereby suspended, effective December 10, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 9, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/5/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

Affidavit of Service

I hereby affirm that on the date and time signed below; this Order to Show Cause and Immediate Suspension of Registration was served on Respondent's authorized representative.

Date _____ Time _____ Diversion Investigator _____

APPENDIX D

DEA ISO for Swedesboro

U.S. Department of Justice
Drug Enforcement Administration

Office of the Deputy Administrator *Washington, D.C. 20537*

IN THE MATTER OF

DEC 0 7 2007

Cardinal Health
1120 Commerce Blvd.
Swedesboro, NJ 08085

ORDER TO SHOW CAUSE AND IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Cardinal Health ("Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RW0269654, pursuant to 21 U.S.C. § 824(d), because Respondent's continued registration constitutes an imminent danger to the public health and safety. DEA Certificate of Registration RW0269654 is assigned to Cardinal Health's Swedesboro, New Jersey, Distribution Center. Notice is also given to afford Respondent an opportunity to show cause before DEA, at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, on April 7, 2008 (if Respondent requests such a hearing), as to why DEA should not revoke such registration pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Respondent's continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. §§ 823(b) and (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following non-exhaustive summary of facts.

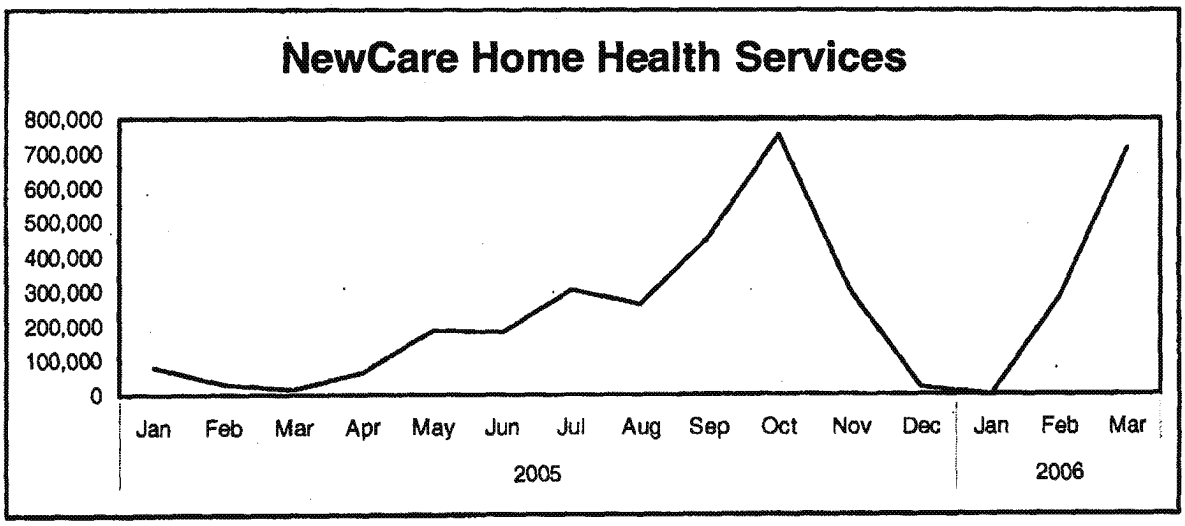
1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA number RW0269654 at 1120 Commerce Blvd., Swedesboro, New Jersey 08085. DEA number RW0269654 will expire on May 31, 2008.

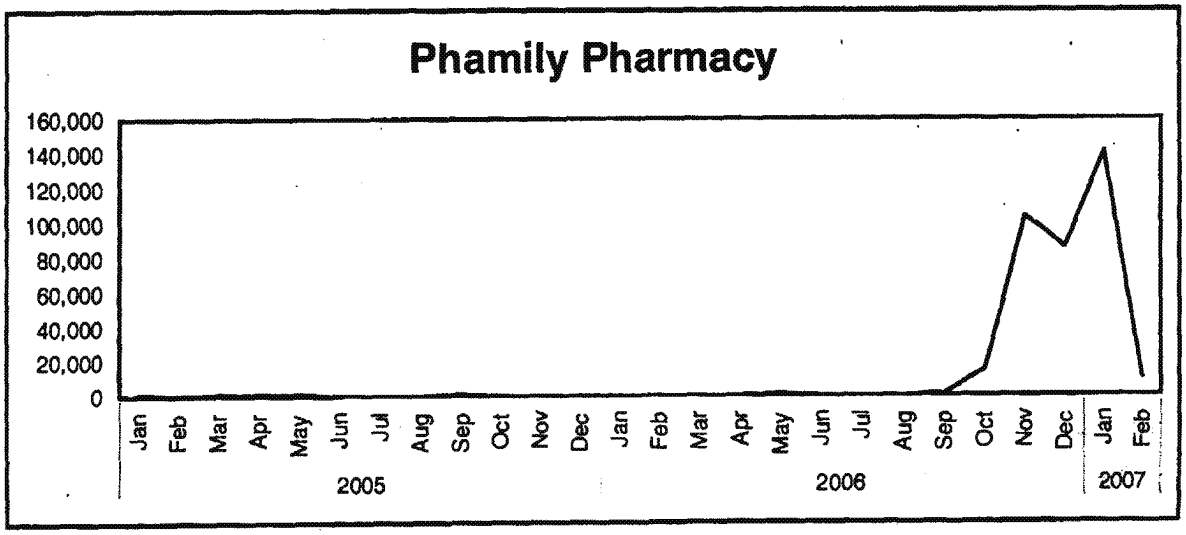
2. Respondent has failed to maintain effective controls against the diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). From January, 2005 through August, 2007, Respondent distributed over 4.5 million dosage units of combination hydrocodone products to customers that it knew or should have known were diverting hydrocodone into other than legitimate medical, scientific and industrial channels. Hydrocodone, in the formulation that Respondent distributed to these customers, is a Schedule III narcotic controlled substance that is addictive and widely abused.

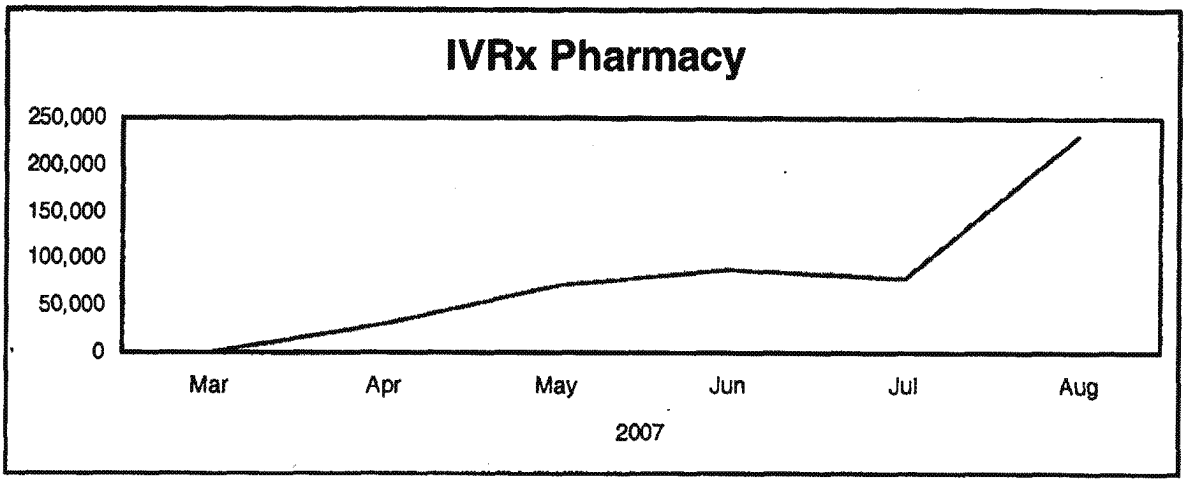
3. Some of Respondent's largest purchasers of combination hydrocodone products were pharmacies engaged in a scheme to distribute controlled substances based on purported

prescriptions that were issued for other than a legitimate medical purpose and by physicians acting outside the usual course of professional practice. These pharmacies distributed millions of dosage units of hydrocodone based on illegitimate prescriptions originating from drug distribution websites, in violation of applicable Federal and State law. *See United Prescription Services, Inc.*, 72 Fed. Reg. 50,397 (2007).

4. Respondent repeatedly distributed hydrocodone combination products to pharmacies engaged in the diversion of controlled substances, i.e., NewCare Home Health Services, Phamily Pharmacy and IVRx Pharmacy. Respondent continually supplied these pharmacies with excessive amounts of hydrocodone under circumstances in which Respondent knew or should have known that these pharmacies were diverting hydrocodone into other than legitimate medical, scientific, and industrial channels. The following graphs reflect the total dosage units of hydrocodone combination products that Respondent distributed to each pharmacy.







5. Respondent distributed hydrocodone to the pharmacies identified in paragraph 4, above, even though Respondent knew that many of the orders placed by the pharmacies were of an unusual size and were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered few, if any, other drug products from Respondent. Respondent knew that pharmacies generally order a wide variety of controlled substances and other drug products from wholesale distributors. Respondent also knew that orders that deviate substantially from a normal pattern were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b). Respondent distributed hydrocodone to each of the named pharmacies even though the pharmacies ordered hydrocodone more frequently than Respondent's other pharmacy customers. Respondent knew that orders of unusual frequency were "suspicious" as that term is used in 21 C.F.R. § 1301.74(b).

6. Respondent repeatedly supplied the pharmacies named in paragraph 4, above, with excessive amounts of hydrocodone despite the substantial guidance provided to Respondent by DEA regarding identifying rogue pharmacies engaged in Internet diversion schemes, and despite the public information readily available to Respondent regarding the pharmacies' association with drug distribution websites, and despite the suspicious nature of the orders placed by these pharmacies. *See Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487 (2007).

IN view of the foregoing, and pursuant to 21 U.S.C. §§ 823(b), (e), and 824(a)(4), it is my preliminary finding that Respondent has failed to maintain effective controls against diversion and that the continued registration of Respondent would be otherwise inconsistent with the public health and safety. Moreover, it is my preliminary conclusion that Respondent's continued registration while these proceedings are pending would constitute an imminent danger to the public health and safety because of the substantial likelihood that Respondent will continue to divert large quantities of controlled substances. Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0269654 is hereby suspended, effective December 13, 2007, at 12:00 p.m. Eastern Standard Time. Such suspension shall remain in effect until a final determination is reached in these proceedings.

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Respondent possesses pursuant to its registration, upon the effective date of the immediate suspension of Respondent's registration. The said Agents and Investigators are also directed to take into their possession Respondent's DEA Certificate of Registration and any unused order forms.

THE following procedures are available to Respondent in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension, Respondent may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Respondent fails to file such a request, the hearing set for April 7, 2008, shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Respondent may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Respondent's position on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Respondent decline to file a request for a hearing or, should Respondent request a hearing and then fail to appear at the designated hearing, Respondent shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Michele M. Leonhart 12/7/07
Deputy Administrator
Drug Enforcement Administration

cc: Hearing Clerk
Office of Administrative Law Judges

APPENDIX E

DEA Show Cause for Houston

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

Washington, D.C. 20537

JAN 3 0 2008

IN THE MATTER OF

Cardinal Health
13651 Dublin Court
Stafford, Texas 77477

ORDER TO SHOW CAUSE

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to afford Cardinal Health ("Registrant") an opportunity to show cause before the Drug Enforcement Administration ("DEA"), at DEA Headquarters located at 600 Army Navy Drive, Arlington, Virginia, at a place and time to be determined, (if Registrant requests such a hearing), as to why DEA should not revoke DEA Certificate of Registration, RC0333524, pursuant to 21 U.S.C. § 824(a)(4), and deny any pending applications for renewal or modification of such registration pursuant to 21 U.S.C. §§ 823(b) and (e), because Registrant's continued registration is inconsistent with the public interest. DEA Certificate of Registration RC0333524 is assigned to Cardinal Health's Stafford, Texas Distribution Center. The basis for this Order to Show Cause is set forth in the following non-exhaustive summary of facts.

1. Registrant is registered with DEA as a distributor in Schedules II-V under DEA number RC0333524 at 13651 Dublin Court, Stafford, Texas 77477. DEA number RC0333524 will expire on May 31, 2008.

2. Registrant distributed massive amounts of particular controlled substances to retail pharmacy customers without maintaining adequate controls to detect and prevent the diversion of controlled substances. For example, from January 2007 through September 2007, Registrant distributed nearly 21 million dosage units of hydrocodone to its retail pharmacy customers. Despite distributing such a large quantity of hydrocodone – a highly addictive and widely abused schedule III controlled substance – Registrant did not have sufficient policies and procedures in place to detect and prevent diversion; did not execute those policies and procedures that were in effect; and failed to provide its employees with the necessary training and resources to detect and prevent diversion.

3. Registrant's distributions of controlled substances to Richmond Pharmacy, AK Pharmacy, and others, were under circumstances that clearly indicated that the pharmacies were engaged in the widespread diversion of controlled substances.

4. Notwithstanding the large quantities of controlled substances ordered by these pharmacies, Registrant failed to conduct meaningful due diligence to ensure that the controlled substances were not diverted into other than legitimate channels. Moreover, Registrant continued to supply the pharmacies with controlled substances without conducting due diligence, notwithstanding that the pharmacies were ordering controlled substances in quantities that far exceeded what traditional retail pharmacies order; that the pharmacies were ordering controlled substances on a more frequent basis than Registrant's traditional retail pharmacy customers; and that Registrant was supplying an inordinate amount of controlled substances versus non-controlled substances to these pharmacies.

5. The direct and foreseeable consequence of Registrant's failure to conduct appropriate due diligence was the likely diversion of millions of dosage units of particular controlled substances.

6. Despite Registrant's policy limiting a retail pharmacy customer's purchases of hydrocodone products to 800 dosage units a day, Registrant frequently distributed hydrocodone in quantities that greatly exceeded this limit. Registrant, however, rarely scrutinized these purchases, and in the few instances where Registrant investigated a particular order, it was frequently done by employees with little or no training in the prevention and detection of diversion and/or by employees with a direct financial interest in the successful completion of the transaction.

7. From January 2, 2007 through September 11, 2007, Registrant distributed approximately 1,381,500 dosage units of hydrocodone to Richmond Pharmacy, or approximately 160,000 dosage units each month. During that period, Registrant distributed hydrocodone to Richmond on 142 days. On each of those days, Richmond's purchase of hydrocodone exceeded the daily limit set by Registrant for its retail pharmacy customers. More recently, on each of the eight days in September in which Registrant shipped hydrocodone to Richmond, Richmond grossly exceeded Registrant's threshold of hydrocodone distributions without scrutiny by Registrant's employees. Registrant distributed 66,000 dosage units of hydrocodone to Richmond on September 4, 2007; 6,000 dosage units on September 5, 2007; 12,000 dosage units on September 6, 2007; 18,000 dosage units on September 7, 2007; 48,000 dosage units on September 10, 2007; 24,000 dosage units on September 11, 2007; and 12,000 dosage units on September 12, 2007. Additionally, on September 17, 2007, Registrant shipped 12,000 dosage units of hydrocodone to Richmond, despite having been notified on September 14, 2007, that Richmond surrendered its DEA registration on September 13, 2007, and was no longer authorized to order or dispense controlled substances.

8. Registrant likewise failed to scrutinize the ordering practices of other retail pharmacy customers who exceeded their monthly limit of hydrocodone purchases and other controlled substances, and continued to distribute massive amounts of controlled substances to these customers despite the fact that these customers routinely exceeded, by huge margins, their monthly limit for purchases of particular controlled substances.

THE following procedures are available to Registrant in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause Registrant may file with the Deputy Administrator of the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. (*See* 21 C.F.R. § 1301.43(a)). If Registrant fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause, Registrant may file with the Deputy Administrator a waiver of hearing together with a written statement regarding Registrant's respective positions on the matters of fact and law involved. (*See* 21 C.F.R. §1301.43(c)).

3. Should Registrant decline to file a request for a hearing or, should Registrant request a hearing and then fail to appear at the designated hearing, Registrant shall be deemed to have waived the right to a hearing and the Deputy Administrator may cancel such hearing, and may enter her final order in this matter without a hearing and based upon the investigative file and the record of this proceeding as it may then appear. (*See* 21 C.F.R. §§ 1301.43(d), 1301.43(e)).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, Washington, D.C. 20537. Matters are deemed filed upon receipt by the Hearing Clerk. (*See* 21 C.F.R. § 1316.45).

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Hearing Clerk
Office of Administrative Law Judges

APPENDIX F

2008 Settlement Agreement - Civil Case

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into by and between the United States Department of Justice, through the United States Attorney's Offices for the Districts of New Jersey, Middle Florida, Southern Texas, Western Washington, Colorado, Northern Georgia, and Central California ("United States") and Cardinal Health, Inc., for itself and on behalf of its subsidiary entities which hold the registrations listed in Attachment A to this agreement (collectively "Cardinal") (each a "Party" and collectively the "Parties").

RECITALS

1. Cardinal is in the business of distributing branded and generic prescription drugs, as well as over-the-counter medications, to retail pharmacies throughout the United States. In furtherance of this business objective, Cardinal operates numerous distribution facilities in the United States, including the seven facilities more fully described in Attachment B to this Agreement ("the Seven Facilities").

2. As described in Attachment A, Cardinal holds Certificates of Registration issued by the Drug Enforcement Administration ("DEA") authorizing it to distribute controlled substances from each of its distribution facilities that handle controlled substances, including the Seven Facilities described in Attachment B.

3. Cardinal is required to operate the Seven Facilities in accordance with the statutory and regulatory provisions of the Controlled Substances Act, 21 U.S.C. § 801 *et seq.* ("the CSA").

4. Each of the Seven Facilities supplies prescription medications, including controlled substances, to retail pharmacies and other health care providers within the respective jurisdictions as stated in Paragraph 8.

5. DEA is the Department of Justice component agency primarily responsible for administering the CSA and is vested with the responsibility of investigating CSA violations.

6. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA in the Districts noted above. *See* 21 U.S.C. § 871 *and* 28 C.F.R. § 0.55(c).

7. Hydrocodone is a medication whose manufacture, distribution, sale and possession is regulated by DEA under the CSA. This includes a requirement to report customer orders for controlled substances that are suspicious as the term is defined under 21 C.F.R. §1301.74(b).

8. The "Covered Conduct" shall mean the following alleged conduct:

A. Within the District of New Jersey: From January 2005 through August 2007, Cardinal-Swedesboro sold more than 4.5 million dosage units of hydrocodone to three pharmacies (IVRx Pharmacy in Springfield, New Jersey; Newcare Home Health Services in Baltimore, Maryland; and Phamily Pharmacy in Washington, D.C.), and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

B. Within the Middle District of Florida: From August 2005 through October 2007, Cardinal-Lakeland sold more than 8 million dosage units of hydrocodone to ten pharmacies in the Tampa area (Medipharm-Rx, Inc., DRM Enterprises, Inc., Jen-Mar Pharmacy Services, Inc., Armenia Pharmacy, Inc., National Pharmacy, Inc., Parulmed Corporation, Q-R-G-, Inc., RKR Holdings, Inc., United Prescription Services, Inc., and Satellite Drug and Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

C. Within the Southern District of Texas: From March 2006 through September 2007, Cardinal-Stafford sold more than 7.5 million dosage units of hydrocodone to fifteen pharmacies in the Houston area (Richmond Pharmacy, AK Pharmacy, Farmacia de Medica, Parkway Pharmacy, Farmacia del Pueblo, Magnum Road Pharmacy, Mastery Pharmacy, Amex Pharmacy #3, Local Pharmacy, HP Pharmacy, I-10 East Pharmacy, Xavier Pharmacy, TXRX Pharmacy, Park Place Pharmacy, and King's Pharmacy) and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

D. Within the Western District of Washington: From March 2007 through November

2007, Cardinal-Auburn sold more than 900,000 dosage units of hydrocodone to Horen's Drugstore, Inc., in Burlington Washington and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

E. Within the District of Colorado: From January 2006 through February 2006, Cardinal-Denver sold large quantities of hydrocodone to Hometown Pharmacy in Trinidad, Colorado, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

F. Within the Northern District of Georgia: From April 2007 through October 2007, Cardinal-McDonough sold large quantities of hydrocodone to Poly-Plex Pharmacy in Atlanta, Georgia, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5);

G. Within the Central District of California: From September 2006 through January 2007, Cardinal-Valencia sold large quantities of hydrocodone to Boulevard Pharmacy in Sun Valley, California, and failed to report these sales as suspicious orders to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5).

9. By entering into this Agreement, Cardinal does not admit to the violations alleged as a result of any DEA investigation, or to any violation of law, liability, fault, misconduct, or wrongdoing.

10. At all times relevant to the activity alleged in these Recitals and Attachments, the CSA (21 U.S.C. § 842(c)(1)) authorized the imposition of a civil penalty of up to $25,000 for most violations of Section 842, but, violations of § 842(a)(5) (record keeping and reporting violations) are subject to a civil penalty of up to $10,000 for each violation.

11. To avoid the delay, expense, inconvenience, and uncertainty of litigation of these claims, the Parties agree to settle, compromise, and resolve all existing or potential claims for civil penalties the United States may have against Cardinal under § 842 of the CSA based on the Covered Conduct as further described in Paragraphs 13 and 14 below.

12. This Agreement is neither an admission of liability by Cardinal nor a concession by the United States that its claims are not well founded. In consideration of the mutual promises, covenants, and obligations set forth in this Agreement, the Parties agree as follows:

TERMS AND CONDITIONS

13. Cardinal shall pay to the United States the sum of Thirty-Four Million Dollars ($34,000,000) (the "Settlement Amount") within thirty (30) days of the effective date of this Agreement, payable as follows:

A. For Conduct Alleged to have Occurred within the District of New Jersey: Cardinal shall pay the sum of Three Million Dollars ($3,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of New Jersey, pursuant to instructions provided by the United States.

B. For Conduct Alleged to have Occurred within the Middle District of Florida: Cardinal shall pay the sum of Sixteen Million Dollars ($16,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Middle District of Florida, pursuant to instructions provided by the United States.

C. For Conduct Alleged to have Occurred within the Southern District of Texas: Cardinal shall pay the sum of Eight Million Dollars ($8,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Southern District of Texas, pursuant to instructions provided by the United States.

D. For Conduct Alleged to have Occurred within the Western District of Washington: Cardinal shall pay the sum of Three Million Five Hundred Thousand Dollars ($3,500,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Western District of Washington, pursuant to instructions provided by the United States.

E. For Conduct Alleged to have Occurred within the District of Colorado: Cardinal shall pay the sum of One Million Dollars ($1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, District of Colorado, pursuant to instructions provided by the United States.

F. For Conduct Alleged to have Occurred within the Northern District of Georgia: Cardinal shall pay the sum of One Million Five Hundred Thousand Dollars ($1,500,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Northern District of Georgia, pursuant to instructions provided by the United States.

G. For Conduct Alleged to have Occurred within the Central District of California: Cardinal shall pay the sum of One Million Dollars ($1,000,000). Payment shall be by electronic funds transfer to the United States Attorney's Office, Central District of California, pursuant to instructions provided by the United States.

14. In consideration of the undertakings by Cardinal, the United States agrees to settle and relinquish all claims for civil penalties it may have under 21 U.S.C. § 842 against Cardinal, its officers, directors, and employees for possible violations of the CSA, and the regulations promulgated thereunder, based on the Covered Conduct.

15. Cardinal fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which it has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the investigation, prosecution and settlement of this matter.

16. Notwithstanding any term of this Agreement, specifically reserved and excluded from its scope and terms as to any entity or person are the following:

A. Any potential criminal liability;

B. Any criminal, civil or administrative claims arising under Title 26, U.S. Code (Internal Revenue Service);

C. Any administrative liability, including mandatory exclusion from any federal programs;

D. Any liability to the United States for any conduct other than that covered by the release in Paragraph 14; and

E. Any claims based on such obligations as are created by this Agreement.

17. Cardinal acknowledges that each of its DEA registered facilities is required to comply

with the controlled substance record keeping and reporting requirements of the CSA. Cardinal represents that it has taken good-faith actions to detect and prevent diversion including agreeing to implement the policies and procedures that are the subject of an administrative settlement agreement between it and DEA.

18. Cardinal agrees that any and all costs it has or will incur in connection with this matter -- including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action -- shall be unallowable costs for government contract accounting and for Medicare, Medicaid, TriCare, and FEHBP reimbursement purposes.

19. This Agreement is not intended by the Parties to be, and shall not be interpreted to constitute, a release of any person or entity not identified or referred to herein.

20. This Agreement shall be governed by the laws of the United States. If a dispute arises under this Agreement between Cardinal and an Office of the United States Attorney signing this Agreement, exclusive jurisdiction and venue shall lie in the federal judicial district of the Office with whom the dispute arose, and to the extent that state law applies to the dispute, the law of the State within the jurisdictional district shall apply. If a dispute arises under this Agreement between Cardinal and more than one of the United States Attorney's Office signing this Agreement, exclusive jurisdiction and venue shall lie in the District of New Jersey and to the extent that state law applies to the dispute, the law of the state of New Jersey shall apply.

21. The Parties agree that this Agreement does not constitute evidence or an admission by any person or entity, and shall not be construed as an admission by any person or entity, with respect to any issue of law or fact.

22. This Agreement constitutes the entire agreement between the Parties and cannot be

amended except in writing and when signed by all the Parties to this Agreement.

23. Cardinal acknowledges that its authorized representatives have read this Agreement and understand that as of its effective date, it will be a matter of public record.

24. Each person who signs this Agreement in a representative capacity warrants that he or she is fully authorized to do so.

25. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). It may be executed in counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement. The government agrees to notify Cardinal immediately when the final signatory has executed this Agreement.

On Behalf of Cardinal Health:

R. Kerry Clark
Chairman and Chief Executive Officer

9/30/2008
Date

Ivan K. Fong
Chief Legal Officer and Secretary

Sept. 30, 2008
Date

John J. Carney, Esq.
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09-30-08
Date

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9/30/08
Date

On Behalf of the United States of America:

Christopher J. Christie
United States Attorney
District of New Jersey

By: Alex Kriegsman
Assistant United States Attorney

10/2/08
Date

Robert E. O'Neill
United States Attorney
Middle District of Florida

By: Javier Guzman
Assistant United States Attorney

9/30/08
Date

Donald J. DeGabrielle, Jr.,
United States Attorney
Southern District of Texas

By: Jill Venezia
Assistant United States Attorney

09/30/2008
Date

Jeffrey C. Sullivan
United States Attorney
Western District of Washington

By: Anastasia Bartlett
Assistant United States Attorney

9/30/2008
Date

Troy A. Eid
United States Attorney
District of Colorado

Amanda Rocque
By: Amanda Rocque
Assistant United States Attorney

9-29-08
Date

David E. Nahmias
United States Attorney
Northern District of Georgia

Mina Rhee
By: Mina Rhee
Assistant United States Attorney

9-29-08
Date

Thomas P. O'Brien
United States Attorney
Central District of California

Shana L. Mintz
By: Shana Mintz
Assistant United States Attorney

Sept. 29, 2008
Date

ATTACHMENT A

ATTACHMENT A

(Cardinal Facilities Referenced in Paragraph 1 of this Agreement)

1. 6012 Molloy Road, Syracuse, New York, operating under DEA registration number PC0003044.

2. 2045 Interstate Drive, Lakeland, Florida, operating under DEA registration number RC0182080.

3. 1240 Gluckstadt Road, Madison, Mississippi, operating under DEA registration number RC0221236.

4. 15 Ingram Boulevard, La Vergne, Tennessee, operating under DEA registration number RC0229965 (Specialty Pharmaceutical).

5. 2512 West Cott Boulevard, Knoxville, Tennessee, operating under DEA registration number RC0238104.

6. 500 Jerry Steele Lane, McDonough, Georgia, operating under DEA registration number RC0271267.

7. 14601 County Road 212, Findlay, Ohio, operating under DEA registration number RC0313940.

8. 5995 Commerce Center Drive, Groveport, Ohio, operating under DEA registration number RC0314891.

9. 13651 Dublin Court, Stafford, Texas, operating under DEA registration number RC0333524.

10. 850 Airpark Drive, Zanesville, Ohio, operating under DEA registration number RC0346658.

11. 6640 Echo Avenue, Suite D, Reno, Nevada, operating under DEA registration number RC0361206 (Specialty Pharmaceutical).

12. 11 Centennial Drive, Peabody, Massachusetts, operating under DEA registration number RD0108200.

13. 71 Mil-Acres Drive, Wheeling, West Virginia, operating under DEA registration number RO0153609.

14. 955 West 3100 South, South Salt Lake City, Utah, operating under DEA registration number RW0191419.

15. 801 C Street NW, Suite B, Auburn, Washington, operating under DEA registration number RW0191813.

16. 7601 N.E. Gardner Avenue, Kansas City, Missouri, operating under DEA registration number RW0191926.

17. 27680 Avenue Mentry, Valencia, California, operating under DEA registration number RW0216449.

18. 2353 Prospect Drive, Aurora, Illinois, operating under DEA registration number RW0231908.

19. 3238 Dwight Road, Elk Grove, California, operating under DEA registration number RW0236009.

20. 2901 Enloe Street, Hudson, Wisconsin, operating under DEA registration number RW0243725.

21. 4 Cardinal Cardinal Health Court, Greensboro, North Carolina, operating under DEA registration number RW0243903.

22. 600 N. 83rd Avenue, Tolleson, Arizona, operating under DEA registration number RW02630056.

23. 4875 Florence Street, Denver, Colorado, operating under DEA registration number RW0263549.

24. 1120 Commerce Boulevard, Swedesboro, New Jersey, operating under DEA registration number RW0269654.

25. 851 Henrietta Creek Road, Roanoke, Texas, operating under DEA registration number RW0279996.

26. 2840 Elm Point Industrial Drive, St. Charles, Missouri, operating under DEA registration number RW0283452.

27. 4220 Hyde Park Boulevard, Niagara Falls, New York, operating under DEA registration number RP0337370 (Parmed Pharmaceuticals).

ATTACHMENT B

ATTACHMENT B

(Seven Cardinal Facilities Referenced in Paragraph 1 of this Agreement)

1. 1120 Commerce Boulevard in Swedesboro, New Jersey ("Cardinal-Swedesboro"), located within the District of New Jersey and operating under DEA registration number RW0269654;

2. 2045 Interstate Drive in Lakeland, Florida ("Cardinal-Lakeland"), located within the Middle District of Florida and operating under DEA registration number RC0182080;

3. 13651 Dublin Court in Stafford, Texas ("Cardinal-Stafford"), located within the Southern District of Texas and operating under DEA registration number RC0333524;

4. 801 C Street NW, Suite B in Auburn, Washington ("Cardinal-Auburn"), located within the Western District of Washington and operating under DEA registration number RW0191813;

5. 4875 Florence Street in Denver, Colorado ("Cardinal-Denver"), located within the District of Colorado and operating under DEA registration number RW0263549;

6. 500 Jerry Steele Lane in McDonough, Georgia ("Cardinal-McDonough"), located within the Northern District of Georgia and operating under DEA registration number RC0271267; and

7. 27680 Avenue Mentry in Valencia, California ("Cardinal-Valencia"), located within the Central District of California and operating under DEA registration number RW0216449.